DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-740/S-019

Bayer Pharmaceutical Division
Attention: Frederich K. Sundermann
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Sundermann:

Please refer to your supplemental new drug application dated April 30, 2001, received May 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol (cerivastatin sodium) tablets.

We acknowledge receipt of your submissions dated May 7, 14, and 17, 2001.

This "Changes Being Effected" supplemental new drug application provides revisions to the **WARNINGS**- Skeletal Muscle, **DOSAGE AND ADMINISTRATION**, and **Patient Information about Baycol** sections of the package insert and patient package insert to emphasize that the starting dose for Baycol is 0.4 mg. The specific changes are as follows:

To the **WARNINGS**, Skeletal Muscle section, the following sentence has been added:

> Beginning therapy above the 0.4 mg starting dose increases the risk of myopathy and rhabdomyolysis.

To the **DOSAGE AND ADMINISTRATION** section, the following paragraph has been added:

> The starting-dose of BAYCOL® is 0.4 mg once daily in the evening regardless of previous lipid therapy. Since the maximal effect of cerivastatin sodium is seen within 4 weeks lipid determinations should be performed at this time and the dose adjusted based upon patient response. Only patients requiring further lipid adjustment should be titrated to 0.8 mg. The dosage range is 0.2 mg to 0.8 mg. In patients with significant renal impairment (creatinine clearance $\leq$60 mL/min/1.73m^2) lower doses are recommended.

To the **Patient Information about Baycol** section, the following sentence has been added:

> If you are taking Baycol for the first time, your daily dose should be 0.4 mg or lower.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 14, 2001, patient package insert submitted May 14, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-740/S-019." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6418.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research